Docket No.: 12013/48803

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT	:	Richard S. KUSLEIKA
SERIAL NO.	:	10/825,309
FILED	:	April 16, 2004
FOR	:	CATHETER FOR TISSUE DILATION AND DRUG DELIVERY
GROUP ART UNIT	:	3763 CONFIRM. NO.: 7747
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PRE-APPEAL BRIEF REQUEST FOR REVIEW

The Applicant respectfully requests pre-appeal brief review of this application. Claim 16, the only independent claim, recites:

> 16. A process for treating tissue at a treatment site within a body lumen, comprising:
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> providing an elongate flexible catheter having a flexible treatment sheath mounted to a distal end region of the catheter and a dilatation balloon within the flexible treatment sheath, wherein the flexible treatment sheath is formed of an elastic material and the dilatation balloon is formed of a substantially inelastic material;
>
> intraluminally advancing the elongate flexible catheter until the flexible treatment sheath is adjacent a predetermined treatment site;
>
> supplying a treatment fluid under pressure to a compartment formed by the treatment sheath, to elastically expand the treatment sheath radially into a substantially conforming contact with the surrounding tissue at the treatment site, cause the treatment fluid to pass through the treatment sheath from the compartment to the surrounding tissue, and maintain the treatment sheath expanded into said contact; and
>
> while maintaining the treatment sheath in said substantially conforming contact with the surrounding tissue at the treatment site, radially expanding the dilatation balloon within the compartment, whereby the dilatation balloon acts radially upon the surrounding tissue through the treatment sheath to effect a dilatation of the surrounding tissue.

The invention as recited in claim 16 clearly sets forth at least two different materials. First, the flexible treatment sheath "is formed of an elastic material." Second, the dilatation balloon "is formed of a substantially inelastic material."

A. Flexible Treatment Sheath Formed of an "Elastic" Material

As described in the specification, the treatment sheath is "elastic" so that it expands "into a substantially conforming contact with surrounding tissue at the treatment site." (Specification, para. 13). "Because of the elasticity of sheath 22, it does not enlarge the artery or otherwise substantially change the shape of the surrounding tissue. Rather, it conforms to the shape and contours of the vessel wall, as seen in FIG. 5." (Specification, para. 52).

The specification gives examples of specific materials that can be used for various embodiments of the "elastic" treatment sheath. It states:

> The sheath advantageously is formed of a biocompatible elastomer having a modulus of elasticity in the range of about 2,000 to 80,000 psi, … . The elasticity is a positive factor in permitting the sheath to stretch in response to encountering tissue surface irregularities.
>
> * * *
>
> Delivery sheath 22 is formed of an elastic biocompatible polymer, e.g. latex. Other suitable materials include polyurethane, silicone, and thermoplastic elastomers. . . . In general, the ability of the sheath to conform to tissue irregularities is a function of the material modulus of elasticity and sheath thickness. Consistent with an adequate tensile strength, lower elastic moduli are preferred. A sheath having a lower modulus of elasticity experiences a greater amount of elastic elongation or "stretch" in response to a given force, i.e. a given fluid pressure of the therapeutic agent in the compartment. In particular, suitable materials will have elastic moduli within a range from about 2,000 psi to about 80,000 psi.

(Specification, paras. 15, 47 (emphasis added)).

B. Dilatation Balloon Formed of a "Substantially Inelastic" Material

In contrast to the "elastic" treatment sheath, the dilatation balloon inside the sheath is "substantially inelastic," giving it a "non-distensible" property whereby it tends to maintain its shape under increased internal pressure. The specification states:

> Preferably the delivery means comprises an elongate and flexible catheter, with the dilatation means comprising a substantially inelastic and fluid impermeable dilatation balloon.
>
> * * *
>
> Dilatation balloon 24 preferably is constructed of a polymeric material that is sufficiently pliable or formable to readily achieve an enlarged state, yet is relatively non-distensible, i.e. tending to maintain it shape under increased fluid pressure within the balloon. Nylon is a preferred material for the dilatation balloon. Other suitable materials include PET, polyolefin, polyethylene, polybutylene terepthalate, PVC, polypropylene and their copolymers.

(Specification, paras. 14, 45 (emphasis added)).

As set forth in the specification, these material properties are important to the intended purpose and operation of the invention:

> Several performance advantages arise from the greater elasticity [of the treatment sheath] and resulting conformity to the tissue. First, wall segment 86 [of the treatment sheath] and the arterial tissues are contiguous over a much greater surface area. As a result a fluid tight seal is formed over the sheath/tissue interface, preventing blood from contacting tissue that is contiguous with the sheath. . . .
>
> Second, the seal enhances concentration of the therapeutic agent along the interface, more specifically that portion of the sheath/tissue interface where pores 56 are formed through the sheath. . . .
>
> Third, the fluid tight seal effectively isolates the therapeutic agent and blood from one another, preventing the loss of efficacy in certain agents caused by contact with blood.

(Specification, paras. 59-62 (emphasis added)).

C. "Elastic" and "Substantially Inelastic"

A person of ordinary skill in the art would understand the difference between the "elastic" material of the treatment sheath and the "substantially inelastic" material of the dilatation balloon. The elasticity of a material is a mechanical property that can be quantified and is typically expressed as the "modulus of elasticity." Materials with a higher "modulus of elasticity" are less elastic. From the claim language, the treatment sheath must have a lower modulus of elasticity so that it is "elastic," and the dilatation balloon must have a substantially higher modulus of elasticity so that it is "substantially inelastic."

The specification makes clear that the treatment sheath is formed of an "elastic" material and the dilatation balloon is formed of a "substantially inelastic" material in order to have the device function in a specific manner. As described above, the treatment sheath is elastic in order to conform to irregularities in the vessel wall for the delivery of the treatment fluid. By contrast, the dilatation balloon is substantially inelastic to effect a dilatation of the surrounding tissue. As would be understood by persons of ordinary skill in the art, substantially inelastic dilatation balloons allow the physician to introduce high pressure forces in the balloon without causing the balloon to expand excessively, thereby allowing the balloon to exert high forces on the vessel wall to effect a dilatation without causing undesirable damage to the vessel.

From the specification, a person of ordinary skill in the art would understand what materials could be used to achieve the described "elastic" treatment sheath and the "substantially

inelastic" dilatation balloon. For the treatment sheath, the specification states that the sheath may be formed, for example, of "an elastic biocompatible polymer, e.g. latex." The specification states that the elastic material may have "a modulus of elasticity in the range of about 2,000 to 80,000 psi." (Specification, paras. 15, 47). For the dilatation balloon, the specification lists possible materials, including, for example, "nylon" and other materials that can be selected as "substantially inelastic" materials. (Specification, paras. 14, 45).

The Applicant respectfully refers to the table that was appended to the Request for Reconsideration filed May 19, 2008. That table shows the modulus of elasticity of various materials. For comparison, the modulus of elasticity of rubber and nylon are shown below:

Material	Modulus of Elasticity (psi)
Rubber	1,450 – 14,500[1]
Nylon	290,000 – 580,000[2]

A person of ordinary skill in the art would plainly understand, from Applicant's disclosure, that a material such as rubber or latex with a relatively low modulus of elasticity is "elastic" within the meaning of Applicant's disclosure, and a material such as nylon or another material with a relatively high modulus of elasticity as compared to the elastic material of the treatment sheath is "substantially inelastic" within the meaning of Applicant's disclosure.

D. <u>The Shockey Device and Request for Reconsideration</u>

The Shockey reference does not disclose using different materials for the inner and outer members, much less different materials as claimed in the Applicant's claims. Shockey discloses an expander member 22 and an inner sleeve 30. Shockey does not state, suggest or even hint at making the expander member 22 and the inner sleeve 30 of different materials, much less making the expander member 22 and the inner sleeve 30 of different materials such that the expander member can be fairly characterized as "elastic" in comparison to a substantially inelastic inner sleeve.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

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[1] The modulus of elasticity of rubber is listed as 0.01×10^9 N/m^2 – 0.1×10^9 N/m^2, which is approximately 1,450 psi – 14,500 psi (using a conversion of 1 N/m^2 = 1.45×10^{-4} psi).

[2] The modulus of elasticity of nylon is listed as 2×10^9 N/m^2 - 4×10^9 N/m^2, which is approximately 290,000 psi – 580,000 psi (using a conversion of 1 N/m^2 = 1.45×10^{-4} psi).

Because Shockey does not disclose a treatment sheath "formed of an elastic material" in combination with a dilatation balloon "formed of a substantially inelastic material," the Applicant respectfully requests withdrawal of the anticipation rejection.

To sustain a rejection based on obvious, there must be "an apparent reason to combine the known elements in the fashion claimed" in the claims at issue. *KSR International Co. v. Teleflex Inc.*, 550 U.S. 1, 14, 82 USPQ2d 1385 (2007). "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970).

Here, Shockey does not disclose or suggest different materials for the inner and outer members, much less an outer member that is "elastic" as compared to a substantially inelastic inner member. The only "reason" for modifying Shockey to arrive at Applicant's claims is through the use of Applicant's own teachings, which is not proper in an obviousness analysis. This is not simply a case of "optimizing" the inner and outer members of Shockey, because nothing in Shockey or elsewhere in the art suggests or even hints that Shockey's inner and outer members should be different from each other. Thus, arriving at Applicant's claims is not simply a matter of adjusting Shockey. Instead, Applicant has invented a novel and nonobvious device which has a treatment sheath which is elastic and a dilatation balloon which, by contrast, is substantially inelastic, in order to achieve the significant advantages that are described in Applicant's specification but not found in or suggested by Shockey or any of the other prior art of record.

In view of the foregoing, the Applicant respectfully requests favorable reconsideration of this application and allowance of all claims. The Commissioner is hereby authorized to charge any fees and credit any overpayments to Deposit Account No. 11-0600.

Respectfully submitted,

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